



# Maryland Department of Agriculture

Office of the Secretary

Robert L. Ehrlich, Jr., Governor  
Michael S. Steele, Lt. Governor  
Lewis R. Riley, Secretary  
John R. Brooks, D.V.M., Deputy Secretary

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December 16, 2005

Division of Dockets Management  
(HFA-305)  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20852

Re: Docket 2002N-0273

Dear Sir or Madam,

I am writing on behalf of the Maryland Secretary of Agriculture Lewis R. Riley to express concerns about the proposed changes to the FDA feed rule for BSE (21 CFR Section 589.2000) and ask you to reconsider implementation of the rule as written. This Department has received numerous inquiries from constituents who produce livestock and poultry as well as those in the allied animal industries expressing concern about the proposed change. Our State Veterinarian shares many of those concerns. Additionally, our Animal Health Diagnostic Laboratory System would be adversely impacted by the proposed a change, as it disposes of some ruminant carcasses by rendering.

Our agency continues to support the FDA mission to protect public health and will continue that support into the future. There are numerous examples of FDA regulations which serve to meaningfully and appropriately mitigate risk to animal and/or public health. In many cases, these regulations come at considerable cost to society, in both economic terms and in compliance effort required of the regulated entities. When there is a demonstrated risk and viable risk mitigation strategy, the associated societal cost is relatively simple to justify.

The proposed rule change does not appear to meet the cost/benefit test discussed above. Regarding an assessment of the risk, extensive surveillance strongly indicates BSE is an extremely rare entity in the United States. Coupled with that is the fact that a very prudent FDA rule change in response to BSE in the United Kingdom, namely the prohibition of feeding ruminant products to other ruminants has greatly reduced if not eliminated the most likely means of BSE transmission in this country. Third, there is little if any evidence that the species which would be prohibited by the proposed change from consuming ruminant products in their feed are susceptible to transmissible spongiform encephalopathies. Finally, there is no available evidence that transmissible spongiform encephalopathies, IF they existed in these non-ruminant species would infect humans. In short, the overall risk this proposed change mitigates is in fact the mathematical product of several very low risks, making the overall risk *extremely* low, almost to the point of being theoretic in nature.

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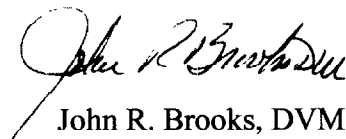
Balanced against the extremely small incremental improvement in food safety and animal health is the rather large societal cost. The economic cost of compliance is driven either by modification in the rendering processes (removal of brain and spinal cord) or by cessation of ruminant rendering altogether. The former increases rendering costs, in an industry with already tight margins and may well lead to the latter which poses real problems for anyone in the animal industry with a need to dispose of ruminant carcasses, including our State Animal Health Diagnostic Laboratory System.

Loss or curtailment of ruminant rendering services will force producers to find alternative disposal mechanisms, many of which were abandoned some time ago in favor of rendering because of environmental, public health and animal health concerns. Animals diverted from the rendering stream will often be lost to the surveillance system intended to detect BSE. Indeed, the perceived risk which led to this proposed change is precisely the reason surveillance data from rendered bovids is more valuable than that from slaughter facilities. Higher risk animals do tend to enter the rendering stream. There is no question about that. The question is "how does one define higher risk?" The answer is that while the risk relative to the slaughterhouse population may be high, the absolute risk of BSE in rendered animals today in the United States is extremely low.

Rendering has been and remains a highly effective means of inactivating or destroying most infectious agents of animals and thus plays a role in promotion of public and animal health. Federal, state and local regulations often limit other disposal methods such as burial, open burning and deposition in landfills. Incineration is expensive and not widely available around our state.

We appreciate the difficulty and complexity of your agency mission and applaud your efforts to promote food safety. We are hopeful this information will be useful in your deliberations on this proposed change. Please feel free to contact me if I can be of assistance in that process.

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Brooks".

John R. Brooks, DVM  
Deputy Directory

cc: Robert Ehart, NASDA  
Gerald Smith, Valley Protein